

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on
issue:

483 M

Board of Directors

Mr Iain Ross

Chairman
Non-Executive Director

Mr Bryce Carmine

Non-Executive Director

Mr Steven Coffey

Non-Executive Director

Dr James Garner

Chief Executive Officer
Managing Director

ASX RELEASE
7 AUGUST 2017

PROGRESS UPDATE ON CANTRIXIL™ (TRXE-002-1) DEVELOPMENT

- Phase I clinical trial in ovarian cancer progressing as planned
- Second batch of Cantrixil planned to be manufactured during third quarter of calendar 2017 to support continuation of the trial
- Patents granted to protect Cantrixil in United States and Europe

Sydney, 7 August 2017 – Novogen Ltd (ASX: NRT; NASDAQ: NVGN), an Australian oncology drug development company, is pleased to provide an update to investors on progress with its clinical-stage development candidate, Cantrixil (TRXE-002-1).

Phase I Clinical Trial in Ovarian Cancer Progressing to Plan

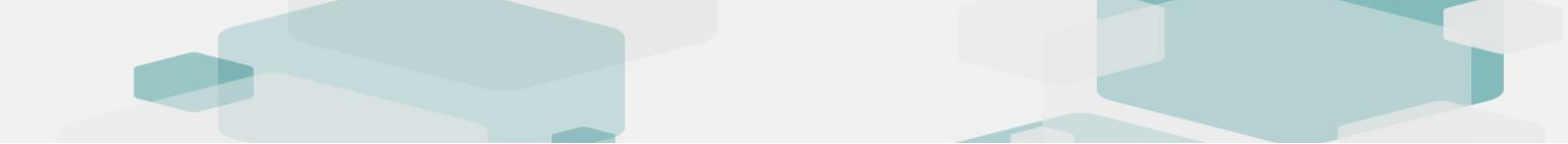
Novogen commenced a phase I clinical trial of Cantrixil in ovarian cancer in December 2016. The study is primarily designed to understand the safety profile of Cantrixil in human subjects, and to establish a Maximum Tolerated Dose (MTD) for the drug.

In accordance with common practice for phase I studies, patients will initially be administered very low doses of Cantrixil, with doses carefully escalated in subsequent patients under careful monitoring by clinicians according to safety and tolerability criteria. Once the MTD has been established, the study will expand recruitment to additional patients in order to further establish safety and explore signals of clinical efficacy.

As at 1st August, the Cantrixil study had successfully progressed through a number of dose levels and participating patients were being carefully monitored for safety. The study continues to recruit patients under the oversight of the investigating clinicians.

Five hospitals are participating in the study, and all sites are open to recruitment, after approval by their respective Human Research Ethics Committees. The participating sites are listed below.

Site	State	Country
Westmead Hospital	NSW	Australia
Flinders Medical Centre	SA	Australia
ICON Cancer Care	QLD	Australia
Peggy & Charles Stephenson Cancer Center	Oklahoma	USA
Mary Crowley Cancer Research Center	Texas	USA



A sixth hospital had originally planned to participate, but withdrew from the study as the clinician due to oversee the trial moved to a different role with another hospital. The withdrawal is not anticipated to have any material impact on the study timeline.

The duration of the study will depend on how many times the dose levels can be escalated before the MTD is established. A higher MTD will result in a longer study, but typically implies a better tolerated drug. Based on the current study progress, Novogen anticipates that it will be able to report the MTD in the first quarter of calendar 2018. It is anticipated that exploratory efficacy data from the additional patients will be available later in calendar 2018.

Novogen CEO, Dr James Garner, commented, “We are pleased with progress to date in the phase I study of Cantrixil. Novogen is fortunate to be working with highly-experienced clinicians at leading trial centers. We remain excited by the potential for Cantrixil to become an important addition to the treatment landscape in ovarian cancer and are grateful to those patients who are participating in the study.”

Novogen looks forward to sharing additional progress reports with investors periodically as the study advances.

Manufacturing

To support continued conduct of the phase I clinical trial in ovarian cancer, Novogen is in the process of engaging a Contract Manufacturing Organization to produce a second batch of clinical trial material under Good Manufacturing Practice conditions. This material will be used to ensure uninterrupted supply to clinical trial sites as the study progresses.

Intellectual Property

The intellectual property portfolio around Cantrixil has been strengthened with the granting of two new patents.

The patent covering Cantrixil has proceeded to grant in the United States on 11 July 2017. In addition, the patent covering Cantrixil has also proceed to grant in the European Union on 2 August 2017. These are important milestones for Cantrixil as they serve to protect the intellectual property associated with the molecule in the world’s largest two markets.

Novogen has applied for patent protection in a total of 25 jurisdictions worldwide, and these applications continue to move forward according to each authority’s specific process.

[ENDS]



About the Cantrixil (TRXE-E-002-1) development candidate

Cantrixil is a cyclodextrin-based formulation of the active ingredient, TRX-E-002-1, which has shown *in vitro* and *in vivo* anti-cancer activity in a range of tumor types. The Company anticipates that, if approved, the drug product would be used as an intra-peritoneal chemotherapy, either alone or in combination with other agents, and in one or more cancers of the abdominal or pelvic cavity (e.g. ovarian, uterine, colorectal or gastric carcinomas). A first-in-human clinical study in patients with ovarian cancer is currently underway.

About Novogen Limited

Novogen Limited (ASX: NRT; NASDAQ: NVGN) is an emerging oncology-focused biotechnology company, based in Sydney, Australia. Novogen has a portfolio of development candidates, diversified across several distinct technologies, with the potential to yield first-in-class and best-in-class agents in a range of oncology indications.

The lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme. Licensed from Genentech in late 2016, GDC-0084 is anticipated to enter phase II clinical trials in 2017. A second clinical program, TRXE-002-01 (Cantrixil) commenced a phase I clinical trial in ovarian cancer in December 2016. In addition, the company has several preclinical programs in active development, the largest of which is substantially funded by a CRC-P grant from the Australian Federal Government.

For more information, please visit: www.novogen.com